Section Five: Packaging

Estimated Contact Time:
45-65 minutes

This module covers:

…how to properly pack and wrap materials for sterilization and storage. Proper packing is important to protect supplies and equipment during processing, and to retain sterility until the items are needed for use.

Following instruction, you should be able to perform the following:

- ☑ Identify packaging materials, methods, and procedures.
- ☑ State packaging requirements.
- ☑ Properly assemble materials for packaging.
- ☑ Demonstrate appropriate wrapping techniques and identify sterile handling and storage requirements.

"Big Things Come In Small Packages"

The main purpose of the packaging process is to protect supplies and equipment during processing and storage so that they remain sterile until they are used on a patient. All of the effort that goes into cleaning, disinfecting, and sterilizing a medical device is wasted if the packaging method and material are not sufficient to prevent microorganisms from returning to the device surfaces.

Basic Packaging Requirements

Although packaging materials may vary from medical center to medical center, and the packaging method is often dictated by the type of equipment you are packaging, there are some basic principles that govern all packaging;

- **Breathable**—Packaging must be breathable to allow the sterilant to penetrate to all device surfaces. It must also allow air, steam, or ethylene oxide to escape during the sterilization process.

- **Maintain sterility**—The package exists to preserve sterility. The packaging material must keep out microorganisms and since they thrive in moisture, it should be moisture resistant with tamper proof seals.
- **Tolerate handling**—Before an item can be used for patient care it must be removed from the sterilizer, stored, and transported to where it is needed. The packaging must withstand repeated handling, resisting punctures and tears, while protecting the package contents. If the packaging does become damaged or torn, it should be easy to see so that the item can be removed from use and reprocessed rather than accidentally being used. Fragile items should be processed in rigid plastic and metal containers to protect them from being crushed or broken.
- **Withstand sterilization**—Vacuum and pressures created during sterilization are extreme. Changes in temperature can cause melting, burning, or warping. The packaging material must be able to stand up to the pressure without bursting, deteriorating, or coming unsealed.
- **Facilitate aseptic delivery**—The best wrap in the world is no good unless the user can access the item when it is needed, without contaminating it. Wraps that make it difficult to remove the product can hinder the quality of patient care. It is helpful if the packaging allows you to tell what is inside without opening it.
- **Good, fast, and cheap**—Because of the volume of use, packaging materials should be inexpensive, readily available, and easy to use. The easier a material is to use, the more likely it is that packages will be wrapped correctly.

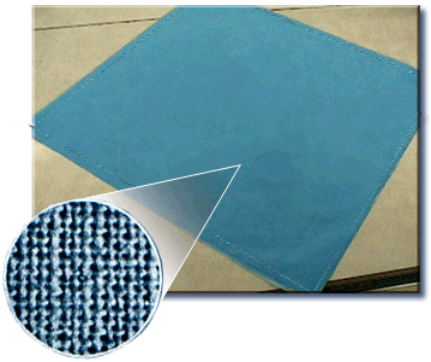
Types of Packaging

There are a number of packaging options. The packaging method and type of material that you use will be determined by:

- the type of item to be packaged
- the item's size and use
- the sterilization method to be used

Too much packaging can inhibit sterilization, while too little will not provide adequate protection.

Textiles



Textiles consist of two layers of fabric sewn together along the edges to create a single wrapper. They come in different types or weights that are distinguished by their thread count—the number of threads woven in a square inch of fabric.

- Muslin is the least efficient with a thread count of 140 or less. It is lightweight and cheap.
- Percale, with a thread count of 140 to 180, is a medium grade fabric that is very common and readily available. Percale is the type of fabric that many bed sheets are made from.
- Pima cotton, with its high thread count of 288, provides an excellent bacterial barrier but is more expensive. It is often treated with quarpel to make it moisture resistant.

Woven textiles require laundering, inspection, delinting, and folding between uses. Because they can be reused, woven wraps may seem cheaper than disposable ones, but the laundering costs and man-hours required to maintain them, make them more costly in the long run. Textile manufacturers recommend that wraps only be laundered 50 to 60 times before being replaced. The number of uses is difficult to track and may result in use of a wrap that has lost most of its barrier capability.

In some medical centers textile wraps are cleaned and serviced by the Laundry, in others SPD is responsible. A light table is required to inspect for holes or damage to woven wraps. Repairs require placing a patch on both sides of the wrap. Patches do not allow penetration of the sterilant and may inhibit sterilization, so large or multiple patches are discouraged.

Non-woven Materials

Non-woven materials come in a variety of types and thicknesses. They are disposable—intended for a single use—and must be discarded afterwards. Disposables can accumulate in landfills, creating environmental concerns. Several manufacturers of disposables have recycling programs. A recycling program must be carefully planned and thoroughly reviewed to prevent any possibility of cross contamination.

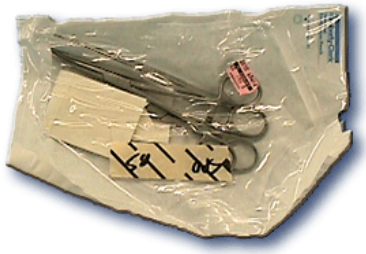
Non-woven packaging materials consist of

- plastic polymers,
- cellulose fibers, or
- pressure-bonded sheets of washed paper pulp.

Plastic polymers are impervious to moisture, but untreated, washed paper pulp can become wet, causing strike through.

Plastic Peel Pouches

Water and water vapor cannot penetrate plastic peel pouches, so they cannot be used for steam sterilization unless they are partially paper. Peel pouches (except for those made from polyvinyl chloride—PVC) may be used for ethylene oxide sterilization. Ethylene oxide does not penetrate well through PVC and the material retains the ethylene oxide after processing.



Plastic films can also be used as dust covers for woven and non-woven wrapped sterile items. A dust cover will protect a properly wrapped, sterilized item from moisture and dust, and extend the shelf life to 1 year. To prevent condensation inside the cover, the item must be completely cool before placing it in the dust cover

Container Systems

Use of container systems is a fairly recent development in the U.S., although they have been used successfully in Europe for decades.

They were developed to meet the need for greater protection of instruments, as they became more complex and more expensive.

Container systems have a metal or plastic outer case, an inner basket constructed of stainless steel, and a gasket along the lid to assure an airtight seal. A filter, consisting of filter paper and a screen or retainer frame to hold it in place, is built into the container lid or bottom. The lid can be removed aseptically to allow for easy access to the inner basket.

Packaging instruments in containers requires less time than wrapping them in traditional linen wraps. After surgery, soiled items can be placed back into the system for safe transportation to the decontamination area.

Tamper proof indicators must be used with all types of containers. Labels, on the end of the containers, identify the name of the set and the sterilization date. Sterilization indicators can be part of the tamper proof label or may be included on the tag used for the sterilization date and technician's initials.

Each time the container is used the gasket and retainer frames must be inspected for damage or wear. If the container uses a valve, it should also be checked to make sure that it is functioning and won't inhibit the sterilization process.

Sterilizer drying times may require adjustment for container loads because metal does not have the ability to absorb moisture like textile wraps do. In mixed loads of both textile wraps and containers, always place containers on the bottom of the sterilizer to avoid condensation forming and dripping down on the textile packages. Don't stack containers on top of each other during the sterilization process, but they may be stacked for storage.

Assembling Items for Packaging

How you stack and layer items is just as important as how you wrap them. You want to package each item as efficiently as possible, taking up the minimum amount of necessary room while ensuring maximum penetration of the sterilant.

Linen Pack Construction

Linen packs come in a variety of sizes and are used mainly in the operating room. Towels and other small packs may be used in clinic or special procedure areas. Linen items must be packaged so that they are easy to remove from the package. Fold gowns inside out so that they can be put on without touching the outside. Fold drape sheets so that they are easy to open and place around the operating site.

Linen packs must conform to the following specifications:

- Density not to exceed 7.2 pounds per cubic foot
- Size not to exceed 12 x 12 x 20 inches
- Arranged in the order in which the items will be used
- Arranged to minimize handling and ensure aseptic presentation at the point of use
- Alternating folds to aid in the air evacuation and steam penetration

At most medical centers, the Laundry Department is responsible for all surgical linen. This includes maintenance and care, and folding and assembly of the surgical linen packs. If laundry service is not available, SPD must fold and de-lint linen in a room that is separate from the preparation room.

Procedure Trays

Procedure trays will be assembled using towels, instruments, small basins, med cups, and gauze. Cards or lists will be supplied listing the required items for each procedure. Wrap the required materials in

muslin or non-woven material and place them on their side during the sterilization process to prevent moisture pooling. Slow moving procedure trays must be placed in dust covers after being processed.

Basin Sets

Basin sets should be constructed so the smaller basins nest inside the larger ones. They should all face the same direction, with a piece of absorbent material between them to facilitate steam penetration and allow for moisture to be wicked away from the metal.

Basins that face in different directions or fit tightly together can trap air and prevent sterilant contact to all surfaces.
Metal ware and linen should not be combined in large packs, since the metal may prevent sterilant penetration of all the linen and prevent proper drying.

Instrument Sets

To allow for safe handling and to ensure adequate exposure to the sterilant, instruments should be processed in a tray. The tray may be packaged in muslin or non-woven wraps, or in a containerized system. Construction of instrument sets will be covered in detail in the Surgical Instrumentation module.

Fragile/Delicate Items

Fragile items or those with small components should be processed in container systems, which provide more protection than other types of packaging. Some container systems come with dividers or inserts so that components can be separated and won't knock against each other during processing.

Wrapping Items

Textile Wraps

Once an item, pack, or instrument set is prepared, the proper size wrap must be selected. Choose a size that will be large enough to completely enclose the items being packaged and to allow all edges and corners to be tucked securely. Wrappers should be just tight

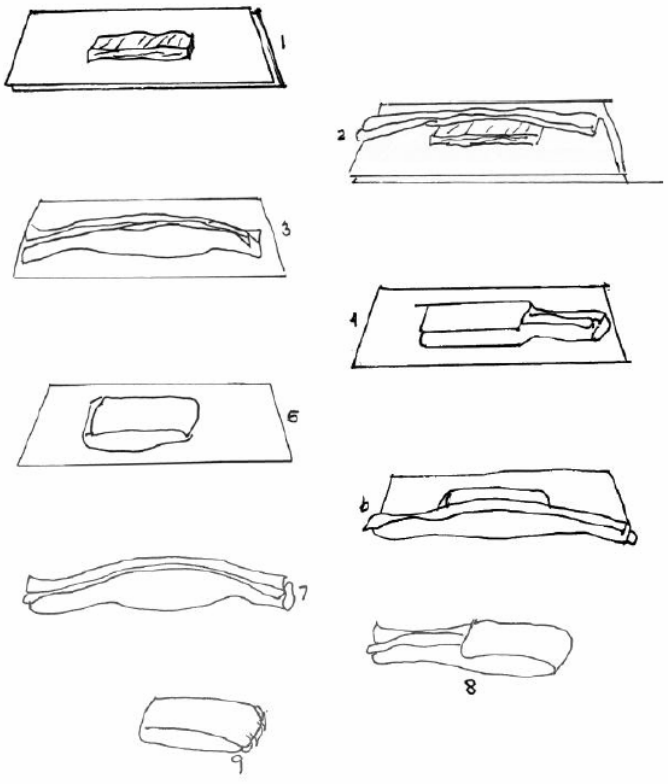
enough to hold the contents together and allow easy penetration of the sterilant.

Items are sequentially wrapped (double-wrapped); one layer at a time, in two separate pieces of textile or non-woven material. The outside wrapper provides a barrier to contamination during handling and acts as a barrier against insects, vermin, and dust. The inside wrap, when opened, may be used as a sterile field.

Proper folding of the wrapper is necessary to secure the package contents and to allow the package to be opened correctly without contaminating the contents. The two most common techniques used for wrapping packs and other medical items are:

- the square fold or straight method
- the envelope fold or diagonal method

SQUARE FOLD

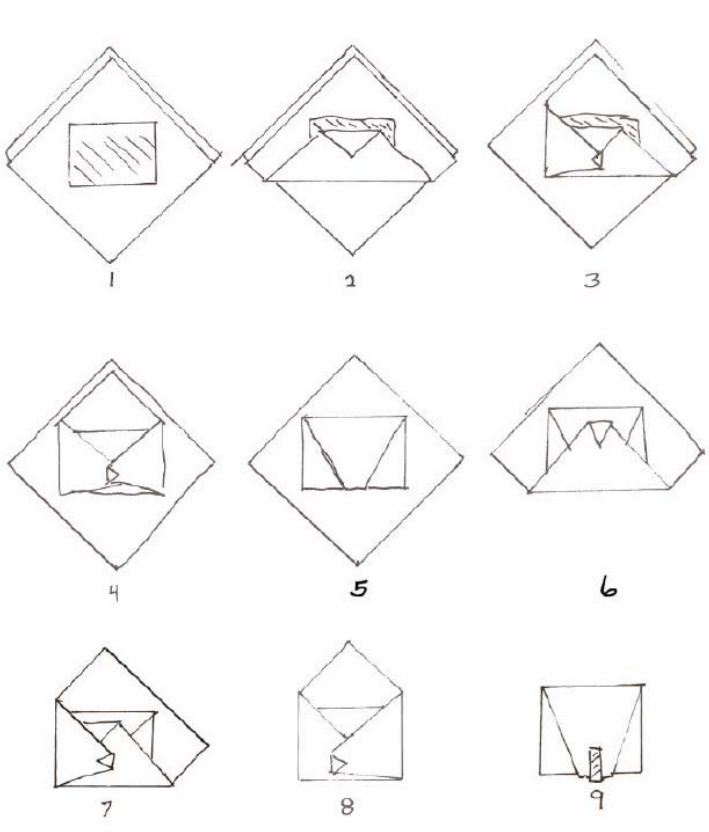


SQUARE FOLD OR STRAIGHT METHOD OF WRAPPING

1. Place two wrappers lengthwise across the table.
2. Place the item in the center of the wrapper.
3. Fold the front edge of the wrapper over the item, covering half of it. Fold the edge back to form a cuff.
4. Fold the back edge of the wrapper over the item. Fold the edge back to form a cuff, overlapping the cuff of the front edge.
5. Fold the left edge of the wrapper over the item, covering half of it. Fold the edge back to form a cuff.

6. Fold the right edge of the wrapper over the item. Fold back the edge to form a cuff overlapping the previous fold.
7. Repeat the entire procedure with the second wrapper. Fold the front edge over and form a cuff.
8. Fold the back edge and form a cuff.
9. Fold the left edge and form a cuff.
10. Fold the right edge and, instead of forming a cuff, bring the edge up and over the item, and secure it with sterilization indicator (autoclave) tape.

ENVELOPE FOLD



ENVELOPE FOLD OR DIAGONAL METHOD OF WRAPPING

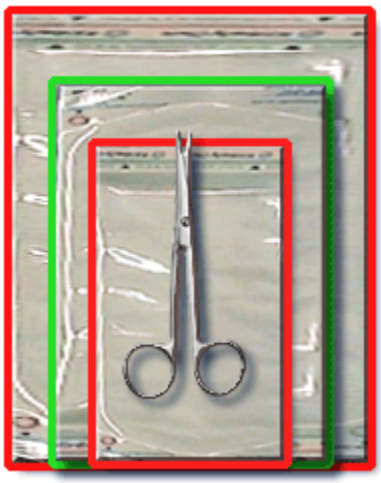
1. Place two wrappers diagonally across the table with one corner pointing to the edge of the table.
2. Place the item in the center of the wrapper parallel to the table edge.
3. Fold the forward corner of the wrapper up over the item, covering half of it. Fold the corner back to form a tab that will be used to open the package.
4. Fold the left corner of the wrapper over the item. Fold the tip back to form a tab.
5. Fold the right corner over the item, overlapping the opposite side. Fold the tip back to form a tab.
6. Fold the back corner of the wrapper over the item and previous folds and tuck the tip under the folds of the left and right corners, leaving a small tab visible for easy opening. *Repeat the process for the second wrapper.*

7. Start with the front corner … then the left corner … then the right corner … and finally the back corner. Instead of tucking the final corner under the others, bring it over the edge of the package and secure it with sterilization indicator tape.

Wraps should be done sequentially—one at a time—and secured with sterilization indicator tape. Use the tape as a place to label and initial the package. Once the package is processed, the tape changes color to indicate that the package has been subjected to sterilization conditions.

Packages should never be secured by string, paper clips, pins, staples, or other sharp objects that could penetrate the surface of the wrapper.

Pouches



Pouches, often called "peel packs" because of the way they are peeled open, are used for items that are too small to wrap or when it is important to be able to see the contents of a package. They are made from a variety of materials, including paper, polyethylene, cellophane, spun-bonded olefin, and various paper/plastic combinations. The most common are preformed paper/plastic with three sides pre-sealed. Choose a size that is right for the object being wrapped. If the pouch is too small it may bulge and burst; if it is too large, it will allow the item to move around and possibly be damaged.

Pouches may also come in rolls, with two sides pre-sealed. This allows you to cut the desired length, insert the item and then seal the top and bottom. A 1-inch section is required above the top seal to facilitate peel down. To provide for proper closure, seals should be at least 3/8 inches wide or double sealed.

Heat is the most common method for sealing pouches. The process bonds the plastic to the paper. After the seal is made you must inspect it to ensure that it is secure. There are several makes and models of heat sealers. Follow the manufacturer's directions for the model you are using.

Some sealing machines operate at high temperatures and can cause burns.

Some pouches are "self-sealing." Paper backing is peeled from an adhesive strip on the flap and the end flap is folded over to close the opening. Place the package on a flat surface and fold the flap over carefully to avoid gaps or wrinkles, which allow microorganisms to enter.

Certain brands of pouches do not seal completely and should not be used. Be certain that any you use are approved for use.

DO NOT secure pouches with anything other than the recommended sealing method. Paper clips, pins, and staples will damage the package integrity. Items packaged in pouches for use in the operating room should be double packaged to allow for delivery to the sterile field. When placing items in a pouch, position them so that the end or handle to be grasped is near the opening of the package. This allows the user to remove the item without contaminating it.

Container Systems

Containers come in a variety of sizes. They are used for surgical instrument sets, small items, and some powered equipment. When using containers:

- Inspect the latches and seals
- Never overload containers
- Clear all items of the hinges and edges when closing
- Wipe down individual containers and process in a washer/decontaminator between uses.

Linens should not be sterilized in containers because there are no studies to support that this is effective.

Labeling

All packages must be labeled in order to tell what is inside, who assembled the package, and when it was done. Proper labeling is necessary for quality assurance, inventory control, and maintaining sterility. Labels should include:

- package contents,
- technician initials,
- service name, and
- sterilizer lot control number which includes shelf life expiration date (added after sterilization).

Hand Written Labels

- ☑ Use felt-tip, indelible ink markers so that the ink does not run, fade, or transfer to the instruments.
- ☑ Record all required information on the tape. Never write on the wrapper.
- ☑ Write on the tape before you put it on the package to avoid damaging the package contents.

Preprinted Labels

- ☑ Indicator tape can be purchased preprinted with the name of high volume items such as towels and 4X4s.
- ☑ Label packages as soon as they are wrapped. If you delay there is a chance that something will be mislabeled.

Labels can be used to manage the shelf life of stored items. Shelf life is the time that an item is expected to remain safe for use. Several things can affect shelf life;

- storage conditions;
- climate and humidity; and
- access to the area.

Any item that has reached the end of its shelf life must be reprocessed and evaluated to determine if it is still needed and will continue to be stocked.

Remember that sterility is event-related rather than time-related. Contamination doesn't suddenly occur on the last day of the labeled shelf life. Factors such as improper handling, inadequate cooling time after sterilization, excessive stacking of items, exposure to extreme climate conditions, the type of material used, and how well the package is sealed, all impact the sterility of an item.

Follow these guidelines for items with a low turnover rate.

Guidelines for Shelf Life	
Item	**Store for**
Woven and non-woven wrapped items with no dust cover	**30 days**
Woven and non-woven wrapped items with a dust cover	**1 year**
Paper/plastic peel pouch	**1 year**
Containerized systems	**1 year**
Commercially sterilized items	**Manufacturer Recommendations**

When an item reaches its expiration date it must be unwrapped and reprocessed.

Summary

Without adequate packaging, the best decontamination and sterilization techniques in the world are useless. Once an item is sterilized, it must remain that way until it is needed for patient care. Wrapped items must be properly handled and stored in order to preserve sterility.

To be effective, packaging material must:

- provide a barrier to dust and microorganisms

- allow for adequate penetration of the sterilant and prevent *wicking* of moisture
- allow proper seals
- withstand normal handling and protect the product
- allow sterile presentation of the contents

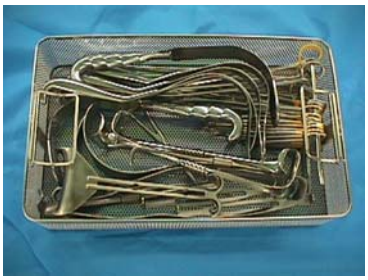
SPD technicians are responsible for knowing the characteristics of the various packaging materials that are available to them and how to use them effectively.

✓ Check What You Know

1. Match each term to its description.

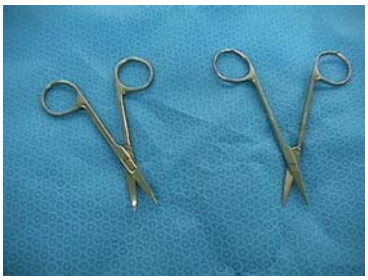
a. container systems	___ Provide more protection for delicate instruments
b. large linen wrap	___ Should be placed on the bottom shelf to avoid dripping condensation
c. peel pouches	___ Useful for packaging large, unwieldy objects such as basin sets
d. non-woven wraps	___ Useful when visibility of item is important
	___ Useful for procedure trays

2. How would you package these items?



Method _____

Method _____



Method _____

3. Where would you place this item on the sterilization cart?

_____

_____

_____

4. Which of the following can impact the sterility of an item? _____
   a. Handling
   b. Cooling time

c. Storage conditions
d. Wrapping material
e. Sealing method
f. Expiration date

5. Most sterilized items should be reevaluated after _____ to determine if they are still needed and are stored in the appropriate location.
    a. their expiration date
    b. 1 month
    c. 6 months
    d. 1 year

6. Package labels should include:
    - ☐ Contents
    - ☐ Expiration date
    - ☐ Storage conditions
    - ☐ Technician initials
    - ☐ Sterilization method